



ASX and Media Release

Viralytics to Present Initial Positive Results of Clinical Trial of CAVATAK™ in Bladder Cancer at Oncolytic Virus Therapeutics Conference

Multiple CAVATAK Presentations Highlight Potential in Range of Cancers

9 June 2015, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today announced that the results of multiple studies of [CAVATAK™](#), including promising early data from its Phase 1/2 clinical trial in bladder cancer, will be presented at the [9th International Conference on Oncolytic Virus Therapeutics](#), to be held June 13 to June 15 in Boston.

CANON Trial

The preliminary results from the first 3 patients in the Phase 1/2 trial referred to as the CANON (CAVATAK in **Non**-muscle invasive bladder cancer) study, demonstrate that administration of CAVATAK via catheter directly into the bladder (intravesicular treatment) is well tolerated with widespread virus replication within the tumour and viral-induced cancer cell death. CAVATAK is an investigational novel cancer immunotherapy based on a proprietary bio-selected common cold virus that has been shown to preferentially infect and attack cancer cells.

The initial trial results are detailed in the following abstract, available at: <http://ovcboston.com/final-program>.

Title: "Oncolytic immunotherapy for the treatment of Non-Muscle Invasive Bladder Cancer using intravesical Coxsackievirus A21: Phase 1/2 CANON study" (Abstract #P-5)

Authors: HS Pandha, N Annels, G Simpson, A Iqbal, D Mansfield, SS Sandu, AA Melcher, KJ Harrington, G Au, M Grose, H Mostafid and D Shafren

"These data from the initial patient cohort are very exciting in achieving proof of concept of intravesicular delivery of CAVATAK", said Professor Hardev Pandha, Principal Investigator of the CANON study and Director of the Surrey Cancer Research Institute at the University of Surrey. "We are seeing viral tumour targeting, virus replication, and evidence of tumour cell death, notably mediated from the administration of the lowest planned dose of CAVATAK. To date the treatment has been well tolerated with no significant toxicity."

Added Prof Pandha, "We are proceeding with the study expecting increased levels of CAVATAK activity in these tumours, not only with higher levels of viral dosing but also when combined with mitomycin C. We are very optimistic that the observed

tumour targeting and viral replication is likely to provide a strong signal in generating both a strong local and systemic anti-tumour immune response.”

[The Phase 1/2 CANON trial](#) is a two-part, open-label, dose-escalation study expected to enrol 30 to 40 patients. The trial is designed to evaluate the safety and tolerability of CAVATAK administered alone, as well as in combination with a sub-therapeutic dose of the standard chemotherapy, mitomycin C. The trial will also assess the pharmacodynamics of CAVATAK and document evidence of anti-tumour activity. Professor Pandha has been actively involved in preclinical research of CAVATAK that has shown that the combination of CAVATAK and mitomycin C synergistically enhanced the cancer-killing activity in bladder cancer cell lines.

“There is a real need for new therapies for bladder cancer that will improve the durability of response and reduce toxicities compared to current treatments,” said Dr Malcolm McColl, CEO and Managing Director of Viralytics. “These positive initial results from the CANON trial suggest that CAVATAK is an oncolytic virus highly suited for application in NMIBC.”

Other Presentations

Additional CAVATAK presentations at the Oncolytic Virus Therapeutics Conference are listed below, with abstracts available at <http://ovcboston.com/final-program>.

The full oral and poster presentations will be available on the Viralytics website following presentation at the conference.

Oral Presentations

Title: “Phase I/II STORM study: Intravenous delivery of a novel oncolytic immunotherapy agent, CAVATAK, in advanced cancer patients” (Abstract #O-51)

Authors: **H.S. Pandha**, C Ralph, K.J. Harrington, A Melcher, M Grose R Karpathy and D Shafren

Title: “Characterisation of the oncolytic kinetics of the immunotherapeutic agent, CAVATAK, delivered intratumorally in patients with advanced malignant melanoma” (Abstract #O-53 and #P-6)

Authors: **R Andtbacka**, B Curti, S Hallmeyer, M Grose, and D Shafren

Title: “Combination of a novel oncolytic immunotherapeutic agent, CAVATAK (Coxsackievirus A21) and immune-checkpoint blockade significantly reduces tumor growth and improves survival in an immune competent mouse melanoma model” (Abstract #O-34)

Authors: G Au, M Quah, Y Wong, and **D Shafren**



Poster Presentations

Title: "Oncolytic Virotherapy for the Treatment of Non-Hodgkin Lymphoma"
(Abstract #P-44)

Authors: M Holmes, G Scott, A Melcher, F Errington-Mais

Title: "Investigation of Coxsackievirus A21 as a Potential Treatment for Pancreatic Cancer" (Abstract #P-86)

Authors: L Smith, D Shafren, G Au

About Viralytics Ltd:

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. Viralytics' lead investigational product, CAVATAK™, is currently being studied in Phase 1 and 2 clinical trials for the treatment of melanoma, as well as prostate, bladder and lung cancers. CAVATAK is a proprietary formulation of the common cold Coxsackievirus Type A21 (CVA21) that preferentially binds to specific 'receptor' proteins highly expressed on multiple cancer types. CAVATAK acts to kill both local and metastatic cancer cells through cell lysis and the potential generation of an immune response against the cancer cells – a two-pronged mechanism of action known as oncolytic immunotherapy.

Based in Sydney Australia, the company is listed on the Australian Securities Exchange (ASX: VLA) while Viralytics' ADRs also trade under VRACY on the US OTCQX International market. For more information, please visit www.viralytics.com.

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